February 21, 2003

John Cherrie, Ph.D.
Department of Environmental and Occupational Medicine
Liberty Safe Work Research Centre
Foresterhill Road
Aberdeen, United Kingdom AB25 2ZP
Telephone: +44(0)1224-558188

RE: Request for Review of Draft Document (*Criteria for a Recommended Standard: Occupational Exposure to Refractory Ceramic Fibers*)

Dear Dr. Cherrie:

Based upon your interest and experience in occupational safety and health, and specifically exposures to airborne fibers and other particulate, your assistance is requested in reviewing the National Institute for Occupational Safety and Health (NIOSH) document referenced above. Enclosed for comment is the draft document characterizing health effects and recommendations regarding occupational exposure to refractory ceramic fiber (RCF). The origins of the draft document date to the early-1990s, when concerns about occupational exposure to airborne RCF were first substantiated by evidence of carcinogenicity in animal studies. In addition, epidemiologic studies of RCF manufacturing workers have reported associations with multiple health effects (pleural plaques, decreased pulmonary function, respiratory symptoms and conditions, and irritation of the skin, eyes, and respiratory tract).

Justification for the criteria document is based on the effects observed in populations with occupational exposure to RCF, and the evidence of carcinogenicity in two animal species, which suggest that RCF should be considered a potential occupational carcinogen. Accordingly, the draft document includes a recommended exposure limit (REL) for airborne concentrations of RCF based on review of independent risk assessments, exposure assessment studies, evidence of health effects from experimental and epidemiologic studies, and analogy with other fibers described in the scientific literature. Other recommendations address informing workers about hazards of exposure to RCF, use of engineering and administrative controls, work practices and hygiene, product reformulation, exposure monitoring, medical monitoring, respiratory protection, and smoking cessation.

The duty of NIOSH to develop criteria documents for specific occupational exposures and workplace conditions derives from the Occupational Safety and Health Act of 1970 (Public Law 91–596). Through the Act, the U.S. Congress charged NIOSH with recommending occupational safety and health standards and describing exposure levels that are safe for various periods of employment, including but not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience. By means of criteria documents, NIOSH communicates these recommended

standards to regulatory agencies (including the Occupational Safety and Health Administration [OSHA]), health professionals in academic institutions, industry, organized labor, public interest groups, and others in the occupational safety and health community. Criteria documents contain a critical review of the scientific and technical information about the prevalence of hazards, the existence of safety and health risks, and the adequacy of control methods.

To assure the highest quality document, the participation of independent experts is requested as part of the review process. The list of external reviewers includes individuals representing government, academia, labor, and industry groups. Comments from external reviewers are officially recorded in the NIOSH Docket, and are subject to public review as mandated by the Freedom of Information Act. We are interested in comments and concerns from reviewers about content, analysis, interpretation, and presentation of information in the document. In recognition and appreciation of the importance of the external review process, we will acknowledge all reviewers in the final draft.

In performing your review of the draft document we would like you to consider the attached list of questions which is provided for your reference. In particular we request that your attention be focused on technical and scientific content. We also note that the bibliography for this document reflects reviews of the literature current through approximately January 2000. We are aware of subsequent publications relevant to this document which will be noted in future revisions of the draft; however, we would like to request your assistance in pointing out particular recent publications which should be included. Finally, although this draft has been subjected to cursory copy editing, subsequent drafts will be scrutinized thoroughly by NIOSH editors. Accordingly, please focus your attention on providing suggestions regarding technical and substantive issues.

Thank you in advance for your review of this NIOSH criteria document. If there are others you feel who might have an interest in reviewing this document, please refer them to the contacts below within the comment period. Should you have technical questions requiring clarification during your review, please contact T.J. Lentz at (513) 533-8260 or TBL7@cdc.gov. Please provide written comments by COB Friday, March 7, 2003 to the NIOSH Docket Office, ATTN: Diane Miller, Robert A. Taft Laboratories, M/S C-34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-8450, fax 513/533-8285. Comments may also be submitted by e-mail to: NIOCINDOCKET@CDC.GOV.

Sincerely Yours,

Paul A. Schulte, Ph.D.
Director
Education and Information Division

2 Enclosures:

Refractory Ceramic Fibers Criteria Document: External review questions for consideration

Overall

- Is there consistency throughout the text?
- Please comment on how accurately and clearly information is presented in the document.
- Is there adequate presentation of original data? Are there additional concerns, issues, or research areas which should be considered?
- Assess the organization of sections and chapters and provide comment.

Human studies

- Please provide a copy of any important reference that should be incorporated into these sections of the document.
- Have the important medical endpoints been adequately discussed?
- Assess the presentation and comparison of data from the U.S. and European cohorts.
- Is the discussion adequate?

Exposure assessment

- Please provide a copy of any important reference that should be incorporated into these sections of the document. Are there additional studies or data characterizing exposure to RCF which should be included?
- What is your impression of the presentation of the exposure data?
- Please identify any data gaps or suggest recommendations for further characterization of RCF exposures.

Animal and in vitro studies

- Please provide a copy of any important reference that should be incorporated into these sections of the document.
- Are the animal studies accurately described and summarized?
- Comment on any additional information that should be included regarding the Maximum Tolerated Dose discussion in the rat chronic inhalation study.
- Comment on any additional information that should be included regarding the association of particle to fiber ratio with tumor formation in the chronic inhalation studies.
- Comment on the NOAEL values presented for fibrosis and lung cancer.
- Comment on the validity of the RCF/amosite comparison using data from two different chronic inhalation studies. Please provide any additional data that should be provided in this comparison.
- Is the discussion of the animal studies adequate? If not, comment on additional information that should be included.
- Are the in vitro studies adequately summarized and explained?
- Is the discussion of the in vitro sections adequate? If not, comment on additional information that should be included.

Basis for the standard

- Is the derivation of the REL adequately explained?

- Assess the use of data collected during the EPA consent agreement to characterize exposure levels in RCF industries and determine achievable levels given engineering controls, work practices, and other considerations. Please provide suggestions or alternative approaches which might improve the presentation, interpretation, and use of these data.
- Are there additional data that should be presented in support of the REL?

Worker protection/recommendations

- Please comment on the recommendations respirator use.
- Are there other engineering controls, work practices, or other factors that should be discussed? (Please specify.)

Medical monitoring

- Please comment on the overall presentation of the medical monitoring program. Is it presented in a logical manner?
- Are there specific elements of the program which should be modified?
- Are there additional elements which could be implemented to help ensure the safety and health of workers?